

On-going access to treatment following the completion of a trial explicitly funded by NHS Shropshire, Telford and Wrekin

(adapted from NHS Commissioning Board Interim Commissioning Policy:
NHSCB cp-07)



Document Control Sheet

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Document Amendment History

Version No.	Date	Brief Description
1	Oct 2013	Approved at Board
2	May 2019	Amended to Joint
3	Sept 2021	Updated due to Merger
4	Sept 2022	Updated following transition to ICB

The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin website: <https://www.shropshiretelfordandwrekin.nhs.uk/about-us/how-we-are-run/policies-procedures-and-governance/medicines-management/medicines-management-commissioning-policies/>

Printed copies or those saved electronically must be checked to ensure they match the current online version.

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Policy Statement

This policy applies to any patient in circumstances where NHS Shropshire, Telford and Wrekin (NHSSTW) is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the NHSSTW is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.

Subject to the terms of this policy, NHSSTW will fund on-going access to the treatment which was the subject of the clinical trial after its completion:

- where the clinical trial has been funded (wholly or in part) by NHSSTW
- where the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient.

Providing funding to continue a treatment to a patient who leaves a clinical trial which has been funded (wholly or in part) by NHSSTW does not represent a policy decision by NHSSTW to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under NHSSTW's *Service Development Policy* in the normal way.

Equality Statement

NHSSTW have a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHSSTW are committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, NHSSTW will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.

The Policy

1. This policy applies to any patient in circumstances where NHSSTW is the responsible commissioner for their NHS care. It equally applies to any patient needing medical treatment where the Secretary of State has prescribed that the NHSSTW is the responsible commissioner for the provision of that medical treatment as part of NHS care to that person.
2. Subject to the terms of this policy, NHSSTW may fund on-going access to the treatment which was the subject of the clinical trial after its completion:
 - where the clinical trial has been funded (wholly or in part) by NHSSTW, **AND**
 - Where the treatment which was the subject of the clinical trial has been demonstrated to deliver clinical benefit to the patient.
3. Providing funding to continue a treatment to a patient who leaves a clinical trial which has been funded (wholly or in part) by NHSSTW does not represent a policy decision by NHSSTW to fund that treatment for other patients who were not part of the clinical trial. Any application for a service development to support funding for the treatment in question will be assessed and prioritised under NHSSTW's *Service Development Policy* in the normal way.
4. Nothing in this policy commits NHSSTW to funding patients who are either involved or have been involved in any other type of clinical trial.
5. Where funding has been provided to a patient under paragraph 2 of this policy, NHSSTW reserve the right to seek a formal clinical review of the patient's present and future healthcare needs and to consider whether the decision to provide the patient with on-going funding for the treatment which was the subject of the clinical trial or any other treatment provided to the patient is equitable and appropriate. NHSSTW shall have regard to its other commissioning policies and its *Ethical Framework* for priority setting and resource allocation when conducting any such review.

Documents which have informed this policy

- NHSSTW's Commissioning Policy: Ethical Framework for priority setting and resource allocation
- The National Specialised Commissioning Group: Funding of treatments for patients leaving clinical trials (March 2008).
- The Medicines for Human Use (Clinical Trials) Regulations 2004. (Statutory Instrument 2004 Number 1031. *The regulations for clinical trials are set out in the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations, as originally passed, have been subsequently amended by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and may be further amended. PCTs are advised to seek advice to ensure that they are consulting the current version of the Regulations.* Original:

<http://www.statutelaw.gov.uk/SearchResults.aspx?TYPE=QS&Title=medicines+for+human+use+%28clinical+trials%29+regulations+2004&Year=&Number=&LegType=All+Legislation>

Amendment: <http://www.opsi.gov.uk/si/si2006/20061928.htm>

- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects. Latest revision: 59th WMA General Assembly, Seoul, October 2008. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
- Department of Health: HSG(97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS.
- Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for subvention (April 2009)
- Department of Health, The National Health Service Act 2006, The National Health Service (Wales) Act 2006 and The National Health Service (Consequential Provisions) Act 2006.
<https://www.legislation.gov.uk/ukpga/2006/41/contents>
- Department of Health, The NHS Constitution for England, July 2009, <https://www.gov.uk/government/publications/the-nhs-constitution-for-england>
- The National Prescribing Centre, Supporting rational local decision-making about medicines (and treatments), February 2009,
- NHS Confederation Priority Setting Series, 2008, <https://www.nhsconfed.org/publications/priority-setting-strategic-planning>

Glossary

TERM	DEFINITION
Clinical trial	A <i>clinical trial</i> is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.
Cost effectiveness	<i>Cost effectiveness</i> is an assessment as to whether a healthcare intervention provides value for money.
Effectiveness - clinical	<i>Clinical effectiveness</i> is a measure of the extent to which a treatment achieves pre-defined clinical outcomes in a target patient population.
Healthcare intervention	A <i>healthcare intervention</i> means any form of healthcare treatment which is applied to meet a healthcare need.
Priority setting	<i>Priority setting</i> is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Prioritisation	<i>Prioritisation</i> is decision making which requires the decision maker to choose between competing options.
Service Development	A <i>service development</i> is an application to NHSSTW to amend the commissioning policy of NHSSTW to provide that a particular healthcare intervention should be routinely funded by NHSSTW for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual

	commissioning round, such investment is referred to as an <i>in-year service development</i> .
Treatment	<i>Treatment</i> means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.